O' 0 9 2005 B I hereby certify that this correspondence is being deposited with the United States Postal Service

Wathington, D.C. 20231
Date of Signature
and Deposit:

Jean C. Baker, Registration No. 35,433

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

the date set forth below as First Class Mail in an envelope addressed to: Commissioner for Patents,

Application. No.:

10/014,724

Applicants:

Michael N. Gould, et al.

Filed:

November 7, 2001

Title:

MONOTERPENES AND SESQUITERPENES AS

CHEMOTHERAPEUTIC AND RADIATION SENSITIZERS AND

IMMUNOMODULATORS

Art Unit:

1618

Examiner: File No.:

Dameron L. Jones

960296.97711

Commissioner for Patents

P O Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. 1.98, enclosed herewith is a list of documents which the Applicants in the above-identified patent application wish to bring to the attention of the Examiner for consideration in connection with the examination on the merits of this patent application.

The information listed in the accompanying Form PTO-1449 and provided herewith may be material to the above-identified application and is submitted in compliance with the requirements of 37 C.F.R. §1.56.

Other Documents

Broitman SA, et al., "Effects of monoterpenes and mevinolin on murine colon tumor CT-26 in vitro and its hepatic 'metastases' in vivo," Adv. Exp. Med. Biol. 401:111-130,

1996. 10/03/2005 HDESTA1 00000104 170055 10014724 Chen Y and Hu D, "Effects of POH in combination with STI571 on the proliferation and apoptosis of K562 cells," J. Huazhon Univ. Sci. Technolog. Med. Sci. 24(1):41, 2004.

Hyer ML, et al., "Synthetic triterpenoids cooperate with tumor necrosis factor-related apoptosis-inducing ligand to induce apoptosis of breast cancer cells," Cancer Res. 65(11):4799-4808, 2005.

Keane MM, et al., "Chemotherapy augments TRAIL-induced apoptosis in breast cell lines," Cancer Res. 59(3):734-741, 1999.

Mo H and Elson CE, "Studies of the isoprenoid-mediated inhibition of mevalonate synthesis applied to cancer chemotherapy and chemoprevention," pp. 567-585, 2004.

Rajesh D, et al., "Perillyl alcohol as a radio-/chemosensitizer in malignant glioma," J. Biol. Chem. 278(38):35968-35978, 2003.

Shi B, et al., "The farnesyl protein transferase inhibitor SCH66336 synergizes with taxanes in vitro and enhances their antitumor activity in vivo," Cancer Chemother.

Pharmacol. 46:387-393, 2000.

Vigushin DM, et al., "Phase I and pharmacokinetic study of D-limonene in patients with advanced cancer. Cancer Research Campaign Phase I/II Clinical Trials Committee," Cancer Chemother. Pharmacol. 42(2):111-117, 1998.

Yu D, "Mechanisms of ErbB2-mediated paclitaxel resistance and trastuzumab-mediated paclitaxel sensitization in ErbB2-overexpressing breast cancers," 28(Suppl. 16):12-17, 2001.

Zhang S, et al., "Anti-cancer potential of sesquiterpene lactones: bioactivity and molecular mechanisms," Curr. Med. Chem. Anti-Canc. Agents 5(3):239, 2005.

International Agency for Research on Cancer (IARC) – Summaries & Evaluations, Lumber and Sawmill Industries (Including Logging) (Group 3) Suppl 7:383, 1987.

Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 17-0055. No additional fees are believed necessary to enter this statement. However, if a fee is necessary please charge Deposit Account No. 17-0055.

Respectfully submitted,

Michael N. Gould, et al.

October , 2005

By:

Jean C. Baker

R¢g. No. 35,433

QUARLES & BRADY LLP

411 East Wisconsin Avenue Milwaukee, WI 53202-4497

(414) 277-5633

(414) 271-3552

Sheet

PTO/SB/08a (07-05)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE Indexthe Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Complete if Known **Application Number** 10/014,724 Filing Date November 7, 2001 First Named Inventor Michael N. Gould Art Unit 1618 **Examiner Name** Dameron L. Jones 960296.97711 **Attorney Docket Number**

U. S. PATENT DOCUMENTS Pages, Columns, Lines, Where Name of Patentee or Examiner **Document Number Publication Date** Cite Relevant Passages or Relevant Applicant of Cited Document MM-DD-YYYY Initials* No.1 Figures Appear Number-Kind Code^{2 (# known)} US-US-US-US-US-US-US-US-US-US-US-US-US-US-US-US-US-US-

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т6	
		***************************************	• • • • • • • • • • • • • • • • • • • •	· · · · · · · · · · · · · · · · · · ·	,		
••••••				•••••••••••••••••••••••••••••••••••••••			
					•••••••••••••		
						\vdash	
						<u>L.</u>	

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08b (07-05)
Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE ork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute fo	or form 1449B/PTO			Complete if Known			
				Application Number	10/014,724		
INFO	RMATION	N DISCLO	SURE	Filing Date	November 7, 2001		
STAT	STATEMENT BY APPLICANT			First Named Inventor	Michael N. Gould		
				Art Unit	1618		
	(Use as many sh	ieets as necessar	y)	Examiner Name	Dameron L. Jones	· · · · · · · · · · · · · · · · · · ·	
Sheet	2	of	3	Attorney Docket Number	960296.97711		

	NON PATENT LITERATURE DOCUMENTS						
Examiner Cite No.1		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.					
		Broitman SA, et al., "Effects of monoterpenes and mevinolin on murine colon tumor CT-26 in vitro and its hepatic 'metastases' in vivo," Adv. Exp. Med. Biol. 401:111-130, 1996.					
	••••••	Chen Y and Hu D, "Effects of POH in combination with STI571 on the proliferation and apoptosis of K562 cells," J. Huazhon Univ. Sci. Technolog. Med. Sci. 24(1):41, 2004.					
		Hyer ML, et al., "Synthetic triterpenoids cooperates with tumor necrosis factor-related apoptosis-inducing ligand to induce apoptosis of breast cancer cells," Cancer Res.					
		Keane MM, et al., "Chemotherapy augments TRAIL-induced apoptosis in breast cell lines," Cancer Res. 59(3):734-741, 1999.					
		Mo H and Elson CE, "Studies of the isoprenoid-mediated inhibition of mevalonate synthesis applied to cancer chemotherapy and chemoprevention," pp. 567-585, 2004.					
:		Rajesh D, et al., "Perillyl alcohol as a radio-/chemosensitizer in malignant glioma," J. Biol. Chem. 278(38):35968-35978, 2003.					
		Shi B, et al., "The farnesyl protein transferase inhibitor SCH66336 synergizes with taxanes in vitro and enhances their antitumor activity in vivo," Cancer Chemother. Pharmacol. 46:387-393. 2000.					
•••••••••••••••••••••••••••••••••••••••		Vigushin DM, et al., "Phase I and pharmacokinetic study of D-limonene in patients with advanced cancer. Cancer Research Campaign Phase I/II Clinical Trials Committee," Cancer Chemother. Pharmacol 42(2:111-117, 1998.					
	•	Yu D, "Mechanisms of ErbB2-mediated paclitaxel resistance and trastuzumab-mediated paclitaxel sensitization in ErbB2-overexpressing breast cancers," 28(Suppl. 16):12-17, 2001					
		Zhang S, et al., "Anti-cancer potential of sesquiterpene lactones: bioactivity and molecular mechanisms," Curr. Med. Chem. Anti-Canc. Agents 5(3):239, 2005.					

1			
	Examiner	Date	
	Signature	Considered]

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08b (07-05) Approved for use through 06/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute Idiziorm 1449B/PTO Complete if Known Application Number 10/014,724 Filing Date INFORMATION DISCLOSURE November 7, 2001 STATEMENT BY APPLICANT First Named Inventor Michael N. Gould Art Unit 1618 (Use as many sheets as necessary) Examiner Name Dameron L. Jones Attorney Docket Number Sheet 3 960296.97711 3

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	1 VIII 1				
		International Agency for Research on Cancer IARC) - Summaries & Evaluations, Lumber and Sawmill Industries (Including Logging) (Group 3) Suppl. 7:383, 1987.			
			••••••		

Examiner Signature		Date Considered			

Examiner	Date		
Signature	Considered	<u> </u>	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.